Remarks/Arguments

In response to the Final Action mailed November 19, 2008, the Notice of Appeal filed May 19, 2009, and the Advisory Action mailed June 2, 2009, Applicants enclose an amendment. By virtue of the filing of a Request for Continued Examination submitted herewith, the enclosed amendment is entered into the application. Favorable consideration of this application is respectfully requested in view of the above amendment and the following remarks.

Claims 1-11 and 13-19 are pending in the application. Claims 1-11 and 13-19 have been rejected. Claims 17-19 have been cancelled without prejudice. New claims 20 and 21 has been added. Support for the language in new claim 20 can be found in the originally filed claims and in the specification, e.g., the paragraph bridging pages 2-3 and page 3, lines 12-39. Support for the language in claim 21 can be found in the specification, e.g., page 12, lines 30-34. It is submitted that no new matter has been added.

Claims 1-11 and 13-16 have been rejected under 35 U.S.C. §102(b) as being anticipated by EP0876815 (EP'815). With respect to EP'815 the Examiner, in the Final Action, states *inter alia*:

> "A reference may be relied on for all it teaches, and is not limited by preferred embodiments or examples. EP'815 clearly teaches embodiments wherein the concentration of the progestogenic compound is about one times the saturation level, and further teaches the importance of keeping the compound dissolved in a low concentration to improve the shelf life. The skilled practitioner would instantly envision values at or just under the saturation level to afford a product with a prolonged shelf life. The teaching of EP'815 meets every limitation of the instant claims."

The Examiner, in the Advisory Action, reiterates the above statements and further states *inter alia*:

> ...The Examiner maintains that one would instantly envision values at or just under the saturation level to afford a product

> with a prolonged shelf life. That EP'815 does not appreciate that keeping the progestogenic compound below the saturation level allows for storage above room temperature is not material to the basis of the rejection. The instant claims do not recite this limitation. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer...Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.....

Applicants respectfully traverse this rejection and submit that claims 1-11 and 13-16 are not anticipated by EP'815.

In response to the Examiner's assertion that EP'815 further teaches the importance of keeping the compound dissolved in a low concentration to improve the shelf life, Applicants would like to point out that keeping the compound dissolved in a low concentration of compound to improve shelf life is technically not what is taught by EP'815. Instead, EP'815 teaches a drug delivery system (DDS) wherein the progestogenic compound is dissolved in the core polymer in a relatively low degree of supersaturation. Applicants would also like to point out that it is the low versus high degree of supersaturation which makes a difference in the shelf life of the EP'815 DDS as is illustrated on page 6, reference example and Table 2, which indicates that at a high degree of supersaturation no stable dosage form can be obtained.

Further, in contrast to the Examiner's assertion that the skilled practitioner would instantly envision values at or just under the saturation level to afford a product with a prolonged shelf life, Applicants assert that one skilled in the art reading the entire disclosure of EP'815 would reasonably interpret the term "at least about one", not at or just under the saturation level, but instead above the saturation level, i.e., above one, e.g., 1.2, for the following reasons.

Claim 4 of EP'815 indicates that the progestogenic compound is dissolved in the thermoplastic core material in an amount by weight of at least about one but not more than about 6 times the amount necessary for obtaining its saturation concentration. Claim 4, however, depends from claim 1 which requires the essential element of "a relatively low degree of supersaturation" of the progestogenic compound in the core. Accordingly, as claim 4 depends from claim 1, claim 4

absolutely requires as an essential element "a relatively low degree of supersaturation." Thus, one skilled in the art reading the limitation "a relatively low degree of supersaturation" together with the limitation "at least about one" would reasonably interpret these phrases together to mean above one since "one" means to one skilled in the art at saturation level and not a low degree of supersaturation.

That the term "at least about one" would be interpreted by one skilled in the art reading EP'815 to be above one is further supported throughout the disclosure of EP'815. To this end, EP'815 expressly states numerous times that the progestogenic compound is dissolved in the core polymer in a low degree of supersaturation (see page 2, line 58 wherein it states "said progestogenic compound being initially dissolved in the core polymer in a relatively low degree of supersaturation; page 3, lines 12-13 wherein it states "...the present invention is based on the surprising finding that a steroid can be retained in a supersaturated sate during prolonged storage..."; page 4, lines 54-55 wherein it states "This example shows that even with etonogestrel at a relatively low degree of supersaturation, a stable dosage form can be obtained"; page 6, claim 1, line 28, wherein it states "...said progestogenic compound being initially dissolved in the said polymer core material in a relatively low degree of supersaturation,..."). Indeed, EP'815 on page 4, lines 6-7 indicates that it is an essential element of the present invention to have the progestogenic steroid dissolved in the core material in a relatively low degree of supersaturation.

Further support that the term "at least about one" with respect to a relatively low degree of supersaturation would be interpreted by one skilled in the art reading EP'815 to be above one is provided in the examples of EP'815. Taking the saturation level of etonogestrel at 25°C in Evatane 28-25 of 0.35% (p. 5, lines 19-21), it can be seen that all of the examples in EP'815 indicate that the relatively low degree of supersaturation means above one (Example 1 is 0.57/0.35=1.6; in Example 2, 0.75/0.35=2.1, and in Example 3 (Table 1) ranging from 0.57/0.35 to 0.75/0.35 which values are above one). None of the examples provided in EP'815 contain a saturation level of etonogestrel equal to one, let alone below one. Indeed, claim 5 (a preferred embodiment of EP'815), in setting forth a specific amount for a low degree of supersaturation, i.e., the amount dissolved is 2 to 5 times

the amount necessary, further supports the proposition that some measure/degree of supersaturation of the progestogenic compound is required in the EP'815 DDS.

In addition, Applicants are also of the opinion that the fact that EP'815 does not appreciate keeping the progestogenic compound below saturation level which allows for storage above room temperature is material to the basis of this rejection for the following reasons. The discovery and design of the EP'815 DDS having one compartment wherein the progestogenic compound is in a concentration above saturation allowed the achievement of a reliable release ratio of the progestogenic and estrogenic compounds over a prolonged period of time, which was previously only accomplished utilizing a plurality of separate resevoirs (see EP'815, page 2, lines 27-53). The present specification indicates that the EP'815 DDS is physically stable only when stored below room temperature (see present specification, page 2, line 29-36). That the EP'815 DDS is physically stable only when stored below room temperature is also supported by the attached package insert (see Attachment 1) for the product Nuvaring®, a commercially available embodiment of the EP'815 DDS. The package insert indicates on page 4, column 3, last paragraph entitled "Storage", that prior to dispensing to the user, Nuvaring® is stored refrigerated 2-8°C. Only after dispensing to the user may Nuvaring® be stored at room temperature (about 25°C) for up to four months. Accordingly, Nuvaring®, having a low degree of supersaturation of etonogestrel above one [see present specification Table 1: Nuvaring® comparative, Evatane 28-25 (core material), etonogestrel at 0.69 wt% together with Table II: Material Evatane 28-25 (core material), saturation level of etonogestrel at 25°C being 0.35 wt%, 0.69/0.35=1.97], if stored at 25°C may eventually crystallize out onto the skin of the device which is undesirable (see present specification on page 17, lines 1-5).

The present invention solves the aforementioned problem of crystallization onto the skin that can occur in the EP'815 DDS when stored at room temperature prior to dispensing to the user by providing an improved DDS as set forth in the presently claimed invention of independent claim 1 having a concentration of etonogestrel below the saturation level at 25°C. The improved DDS of the presently claimed invention is physically stable (progestogenic compound does not crystallize onto the skin) under room temperature conditions, and thus does not require special storage and transportation conditions at a temperature below room temperature as is required for the EP'815

DDS (see specification on page 3, lines 36-39). Accordingly, the DDS of the presently claimed invention having a concentration of etonogestrel below the saturation level at 25°C can be stored at 25°C prior to dispensing the DDS to the user, whereas the EP'815 DDS having a low degree of supersaturation of etonogestrel may not be stored at 25°C prior to dispensing the DDS to the user in view of allowing a reasonable storage time at room temperature for the user. Accordingly, the subtle difference in concentration between the EP'815 DDS and the presently claimed DDS, results in a difference in the physical stability of the DDS's when stored below room temperature prior to dispensing the DDS to the user. Thus, the property of physical stability of the presently claimed DDS at 25°C as discussed above is not present in the EP'815 DDS, and thus is not an inherent property of the EP'815 DDS. In sum, the DDS of the presently claimed invention is not identical to the DDS described in EP'815, and thus the presently claimed DDS is not anticipated by the EP'815 DDS.

It is further submitted that new claim 20 (dependent on claim 1) directed to a DDS which further recites the feature "...wherein the DDS is physically stable when stored on or above room temperature" is patentable over EP'815 as the EP'815 DDS is not identical nor possesses the aforementioned feature exhibited by the presently claimed DDS.

In view of the above, withdrawal of the rejection of claims 1-16 under 35 U.S.C. §102(b) is respectfully requested.

Claims 17-19 have been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. As claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the objection to claims 17-19 is respectfully requested.

Claims 17-19 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation of "between 0.1 and 1.0 wt%". Since claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the rejection of claims 17-19 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 17-19 have been rejected under 35 U.S.C. §102(b) as being anticipated by van Laarhoven et al., International J. of Pharmaceutics, 2002, 232, 163-173). Since claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the rejection of claims 17-19 under 35 U.S.C. §102(b) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Dated: December 21, 2009

Respectfully submitted,

By _____

Organon International Inc.
Patent Department
c/o Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey
K-6-1; MS 1990
Tel: (908) 298-2161
Fax: (908)-298-5388

Susan Hess
Registration No.: 37,350
Attorney For Applicant(s)

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Attachment 1 -Nuvaring® package insert